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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,312	02/28/2000	Takahide Kasai	31671-157328RK	8281

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EXAMINER

AHMED, HASAN SYED

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/514,312	KASAI ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-51, 62, 63 and 70-72 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 45-51, 62, 63 and 70-72 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt is acknowledged of Applicants' amended claims, remarks, and arguments filed on 7 June 2006.

The 35 U.S.C. 112 rejection of record pertaining only to the phrase "yeast cell wall fractions" is hereby withdrawn in light of the amended claim set.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45-51, 62, and 63 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the phrase "cell residue of yeast" renders the claims indefinite because it is not clear which particular residue or residues of the yeast cell are being referred to.

Moreover, the phrase "yeast cell wall fractions" renders the claims indefinite because the properties of the fractions being claimed have not been delineated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45-51, 62, 63, remain 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shank (US 4,001,480) in view of Jamas, et. al. (US 4,962,094).

Shank provides a product, such as a drug, condiment or vitamin, encapsulated within biological capsules provided by microorganisms, such as yeast (col. 1, line 46 – col. 2, line 51). Shank teaches that the yeast cell wall may be softened by treatment with proteolytic enzymes, and then hardened with dilute aldehydes (col. 5, lines 28-50). In the examples provided, Shank teaches that the encapsulated material is cast upon an acidified paper (see examples I-V).

Shank does not include a plasticizer in the composition of the invention. However, the Jamas reference does include a plasticizer.

Jamas, et. al. provide a composition and method of utilizing glucan as a dietary additive (see abstract). According to the reference, “[w]hole glucan can be treated with an acid, such as acetic acid, after its extraction from yeast to reduce the degree of $\beta(1-6)$ crosslinking, thereby increasing the water holding capacity of the whole glucan.” (col. 4, lines 31-35).

Jamas, et. al. teach that the dietary additive of the invention can be administered orally. The glucan can be administered alone or with other ingredients. The compositions of the invention can be in the form of a tablet or powder, and include additives for coating, such as a plasticizer (col 5, lines 27-63; col 6, line 18).

Thus, it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the invention to combine the compositions and methods disclosed by Shank (particularly use of proteolytic enzymes), with the composition taught by Jamas,

et. al (particularly use of an acid, and use of a plasticizer for oral administration in tablet form.) The expected result would be more effective softening of the yeast cell wall.

Response to Arguments

Applicant's arguments filed 7 June 2006 have been fully considered but they are not persuasive.

1. Regarding the 35 U.S.C. 112 rejection-of-record pertaining to the phrases "cell residue of yeast" and "yeast cell wall fractions," the amendments do not render these phrases definite. It remains unclear exactly what comprises "cell residue of yeast" and "yeast cell wall fraction."

2. Applicants argue that the Shank reference "...does not suggest or disclose that, following the treatment with enzymes, (1) the yeast are treated with a solution that allows internal soluble cell constituents to exit from the yeast; (2) the yeast are treated with an acidic aqueous solution; or (3) the treatment with an acidic aqueous solution is followed by a step...to separate the cell residue from the internal soluble cell constituents.

The rejection-of-record is 35 U.S.C. 103 obviousness as taught by Shank in view of Jamas, et. al., not 35 U.S.C. 102 anticipation as disclosed solely by Shank. The Shank reference is relied upon to show that the concept of coating a solid material with yeast cell wall fractions and treatment of the cell wall with proteolytic enzymes is known in the art (col. 1, line 46 – col. 2, line 51; col. 5, lines 28-50). The Jamas, et. al. reference is relied upon to show that the concept of treating yeast cell fragments with enzymes and acidic aqueous solution followed by a separation step was known in the

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art (col. 2, lines 3-14; col. 4, lines 31-40; Example 2). The combined teachings of these two references render the instant application, as claimed, obvious.

3. Applicants argue that the Jamas, et. al. reference does not teach that the treatment of yeast with an aqueous acidic solution, followed by a separation step can be used to remove internal soluble cell constituents from the yeast to provide a coating agent.

Jamas, et. al. teach treatment of yeast fragments (whole glucan) in a 0.5 M acetic acid solution that is stirred continuously for 3 hours at 90°C, followed by centrifugation at 5000 rpm for 20 minutes, followed by a wash step with distilled water, followed by a wash step in ethanol and two wash steps in dehydrated ethyl ether (Example 2). Although the Jamas, et. al. reference does not explicitly teach removal of internal soluble cell constituents, it is difficult to imagine that any would remain after such a rigorous regimen. Furthermore, Shank, not Jamas, et. al. was relied upon to teach the concept of coating a solid material with yeast cell wall fractions.

4. Applicants argue that the combination of Shank and Jamas, et. al. does not render the claimed invention obvious.

The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

Claims 45-51, 62, 63 and 70-72 remain rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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